

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
2 May 2002 (02.05.2002)

PCT

(10) International Publication Number  
WO 02/034310 A3

(51) International Patent Classification<sup>7</sup>: A61L 31/04,  
31/14, 27/14, 27/50

(21) International Application Number: PCT/US01/45406

(22) International Filing Date: 23 October 2001 (23.10.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
09/696,389 25 October 2000 (25.10.2000) US

(71) Applicant (for all designated States except US): SDGI  
HOLDINGS, INC. [US/US]; 300 Delaware Avenue, Suite  
508, Wilmington, DE 19801 (US)

(72) Inventors; and

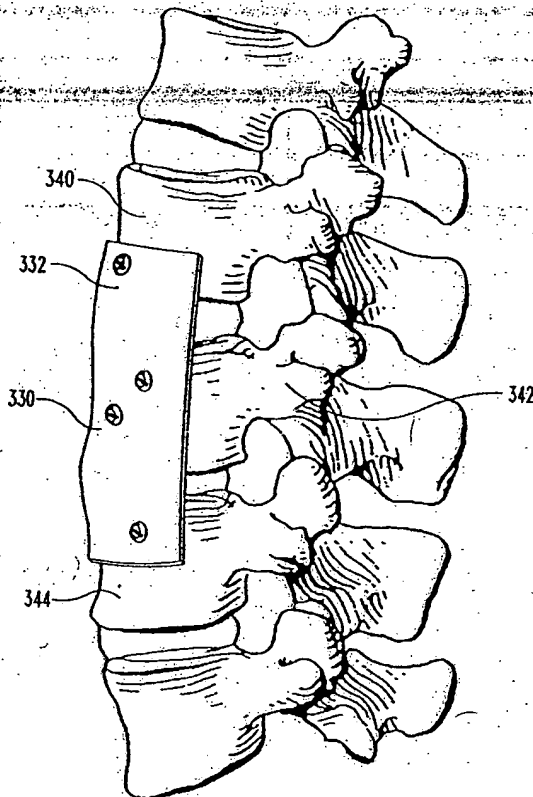
(75) Inventors/Applicants (for US only): DICKSON, An-  
drew, M. [US/US]; 128 Hidden Cove Court, Gallatin,  
TN 37066 (US). ESTES, Bradley, T. [US/US]; 4712  
American Drive, Durham, NC 27705 (US).

(74) Agents: MYERS, James, B., Jr. et al.; Woodard,  
Emhardt, Naughton, Moriarty & McNett, Bank One Cen-  
ter/Tower, Suite 3700, 111 Monument Circle, Indianapolis,  
IN 46204 (US).

(81) Designated States (national): AE, AG, AL, AM, AT, AU,  
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,  
CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH,  
GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC,  
LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW,  
MX, MZ, NO, NZ, PH, PL, PT, RO, RU, SD, SE, SG, SI,  
SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU,  
ZA, ZW.

[Continued on next page]

(54) Title: SELF-FORMING ORTHOPEDIC IMPLANTS



(57) Abstract: This invention relates to a self-forming ortho-  
pedic implant (10, 40, 60A/B, 100, 140, 200, 250, 280 and  
330). The implant is formed a shape memory polymer. The  
implant can be provided in an original configuration selected to  
facilitate orthopedic treatment of bone defects, fixation of bone  
fragments and fractures, or selected to induce bone structures  
to conform to a desired anatomical configuration. Non-limit-  
ing examples of preferred configurations include bone spacers  
or bone plates, connective tissue replacements (i.e., tendons,  
ligaments, and/or cartilage). In preferred forms, the implant is  
deformed to an alternative configuration prior to implantation.  
Upon application of selected stimuli, for example, heating the  
implant to a temperature where the shape memory polymeric  
material becomes elastic induces the implant to revert to its  
original configuration. In use, when the implant is subjected  
to the selected stimuli, it conforms to a selected bone tissue  
or alternatively conforms to a configuration that urges bone  
structures into a desired alignment and/or configuration. When  
used to replace connective tissues, the implant exhibits a ten-  
sile strength to allow the adjacent bone structure to articulate,  
yet provides sufficient force to urge the bone structures into a  
desired position and alignment.

WO 02/034310 A3



(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

— with amended claims

(88) Date of publication of the international search report:  
17 October 2002

Date of publication of the amended claims: 20 February 2003

Published:

— with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

## AMENDED CLAIMS

[received by the International Bureau on 27 September 2002 (27.09.02);  
original claims 1-88 replaced by new claims 1-80 (9 pages)]

1. An orthopedic implant for a bone structure, said implant comprising a deformable body defining a spinal spacer for implantation between adjacent vertebrae and  
5 formed of a shape memory polymeric material, said body provided in a first configuration and capable of deforming to a second configuration upon application of selected stimuli, wherein said second conformation at least a portion of said body matingly conforms to a portion of the bone structure.
- 10 2. The implant of claim 1 wherein the body in the first configuration has a first external volume and in the second configuration has a second external volume greater than the first external volume.
- 15 3. The implant of claim 1 wherein the body in the first configuration has a first external volume and the body in the second configuration has a second external volume less than the first external volume.
- 20 4. The implant of claim 1 wherein the body includes an internal cavity for receipt of an osteogenic material.
5. The implant of claim 1 wherein the body defines a flexible connecting member between two or more adjacent bone portions.
- 25 6. The implant of claim 1 wherein said body is provided in an original configuration.
7. The implant of claim 6 wherein said second confirmation is substantially equivalent to said original configuration.
- 30 8. The implant of claim 1 wherein the body deforms to said second configuration upon implantation.

9. The implant of claim 1 wherein said body in said second configuration promotes fixation of two or more bone portions.

5 10. The implant of claim 1 wherein said body contacts two or more adjacent bone portions and in said second configuration permits articulation between the two or more adjacent bone portions.

11. The implant of claim 1 wherein said body in said first configuration is secured to one or more bone portions prior to deforming to the second configuration.

10

12. The implant of claim 1 wherein the bone structure includes a cavity and said second configuration matingly conforms to the cavity in the bone structure.

13. The implant of claim 1 wherein the shape memory polymeric material is  
15 elastic at a deformation temperature and said selected stimuli includes heating the body to a temperature equal or greater than the deformation temperature.

14. The implant of claim 13 wherein the deformation temperature is between about 38° C and about 65° C.

20

15. The implant of claim 15 wherein the deformation temperature is between about ambient temperature and 65° C.

16. The implant of claim 1 wherein the shaped memory polymeric material is  
25 biodegradable.

17. The implant of claim 1 wherein the shaped memory polymeric material is non-biodegradable.

30

18. The implant of claim 1 wherein the shaped memory polymeric material is selected from the group consisting of: polylactide, polyglycolide, poly(lactide-co-glycolide), polyurethane, poly(ethylene-co-vinyl acetate), poly(ethylene-co-propylene), poly(ethylene-

co-propylene-co-diene), poly( $\epsilon$ -caprolactone), poly( $\beta$ -hydroxybutyrate), poly( $\beta$ -hydroxybutyrate-co-hydroxyvalerate), poly(methacrylate), poly(methyl methacrylate), poly(acrylate), and mixtures, copolymers and blends thereof.

5           19. An orthopedic implant for two or more adjacent bone portions said implant comprising a body formed of a material comprising a biodegradable shape memory polymer, said body provided in a first configuration and adapted to bear against at least one of said adjacent bone portions, wherein said body deforms upon application of selected stimuli to a second configuration to apply a force to said adjacent bone portions.

10

20. The implant of claim 19 wherein said force is a compressive force on the adjacent bone portions.

15

21. The implant of claim 19 wherein said body exhibits a desired tensile strength to replace a tendon or ligament for said two or more adjacent bone portions.

22. The implant of claim 19 wherein the implant includes a bone plate.

23. The implant of claim 19 wherein the body defines a bone spacer.

20

24. The implant of claim 19 wherein the body defines a flexible connective member between the adjacent bone portions.

25

25. The implant of claim 19 wherein the body comprises a cavity for receipt of an osteogenic material.

26. The implant of claim 19 wherein said body in said second configuration promotes fixation of the adjacent bone portions.

30

27. The implant of claim 19 wherein said body permits articulation between adjacent bone portions.

28. The implant of claim 19 wherein the shape memory polymer is elastic at a deformation temperature and said selected stimuli includes heating the body to a temperature equal to or greater than the deformation temperature.

5 29. The implant of claim 19 wherein the deformation temperature is between about 38° C and about 65° C.

30. The implant of claim 19 wherein the deformation temperature is between about ambient temperature and 65° C.

10

31. The implant of claim 19 wherein the shaped memory polymeric material is selected from the group consisting of: polyurethane, poly(ethylene-co-vinyl acetate), poly(ethylene-co-propylene), poly(ethylene-co-propylene-co-diene), poly(methacrylate), poly(methyl methacrylate), poly(acrylate), and mixtures, copolymers and blends thereof.

15

32. An orthopedic implant comprising a non-biodegradable body formed of a shape memory polymeric material and comprising at least one surface adapted to bear against bone tissue wherein said body is provided in a first configuration and upon heating to a deformation temperature said body deforms to a second configuration.

20

33. The implant of claim 32 wherein the body in the first configuration has a first external volume and in the second configuration has a second external volume greater than the first external volume.

25

34. The implant of claim 32 wherein the body in the first configuration has a first external volume and the body in the second configuration has a second external volume less than the first external volume.

30

35. The implant of claim 32 wherein the body defines bone plate.

36. The implant of claim 32 wherein the body defines bone spacer.

37. The implant of claim 32 wherein the body defines a flexible connective member.

5 38. The implant of claim 32 wherein said body is provided in an original configuration.

39. The implant of claim 32 wherein the body self deforms to said second configuration upon implantation.

10 40. The implant of claim 32 wherein the deformation temperature is between about 38° C and about 65° C.

41. The implant of claim 32 wherein the deformation temperature is between about ambient temperature and 65° C.

15 42. The implant of claim 32 wherein said body in said second configuration permits articulation between adjacent bone portions.

20 43. The implant of claim 32 wherein said second configuration matingly conforms to a cavity in the bone tissue.

44. An orthopedic implant for bone tissue said implant comprising body formed of a material comprising a shape memory polymer provided to elastically deform at a deformation temperature, said body provided in a first configuration selected to facilitate  
25 implantation and deformable to a second configuration upon heating to a temperature equal to or greater than the deformation temperature, said second configuration provided to facilitate orthopedic treatment.

30 45. The implant of claim 44 wherein the body in the first configuration has a first external volume and in the second configuration has a second external volume greater than the first external volume.

46. The implant of claim 44 wherein the body in the first configuration has a first external volume and the body in the second configuration has a second external volume less than the first external volume.

5 47. The implant of claim 44 wherein the body defines a bone spacer.

48. The implant of claim 44 wherein the body defines bone plate.

10 49. The implant of claim 44 wherein the body defines a flexible connective member.

50. The implant of claim 49 wherein the body connects the bone tissue to a second tissue selected from the group consisting of: bone tissue, ligament tissue, tendon tissue and cartilage tissue.

15

51. The implant of claim 49 wherein the body is adapted to replace a portion of ligament tissue, tendon tissue or cartilage tissue.

20

52. The implant of claim 49 wherein the body includes tissue promoting growth factors.

53. The implant of claim 44 wherein the body self deforms to said second configuration upon implantation.

25

54. The implant of claim 44 wherein said body is provided in an original configuration.

55. The implant of claim 44 wherein the deformation temperature is between about 38° C and about 65° C.

30

56. The implant of claim 44 wherein the deformation temperature is between about ambient temperature and 65° C.



57. The implant of claim 44 wherein the deformation temperature is below normal body temperature.

5 58. The implant of claim 44 wherein said body in said second configuration permits articulation between adjacent bone portions.

59. The implant of claim 44 wherein said second configuration matingly conforms to a cavity in the bone tissue.

10

60. A spinal spacer for insertion into a spine, said spacer formed of a material including a shape memory polymer and movable between a first configuration and a second configuration by action of the shape memory polymer.

15

61. The spacer of claim 60 provided in an original configuration.

62. The spacer of claim 61 wherein the second configuration is substantially equivalent to said original configuration.

20

63. The spacer of claim 60 wherein said second configuration is larger than said first configuration.

64. The spacer of claim 60 inserted into a disc space.

25

65. The spacer of claim 60 inserted into a vertebral body.

30

66. An orthopedic implant comprising a body adapted to contact a vertebral bone and said body formed from a non-biodegradable material comprising a shape memory polymer and movable between a first configuration and a second configuration by action the shape memory polymer.

67. The implant of claim 66 wherein said body defines a spacer.

68. The implant of claim 66 wherein said body defines a bone plate.

69. The implant of claim 66 wherein said body defines a flexible connective  
5 member between the vertebral bone and a second tissue.

70. The implant of claim 66 wherein the second tissue comprises bone tissue.

71. The implant of claim 66 wherein the second tissue comprises ligament tissue.

10 72. The implant of claim 66 wherein the second tissue comprises tendon tissue.

73. A method of orthopedic treatment of a bone defect, said method comprising:  
selecting an orthopedic implant comprising a deformable body provided in a first  
15 configuration and formed of a shape memory polymeric material  
contacting said implant to the bone defect;  
stimulating said implant to deform said body to a second configuration.

74. The method of claim 73 wherein said shape memory polymeric material is  
20 provided to elastically deform at a deformation temperature and wherein said stimulating  
comprises heating said shape memory polymeric material to a temperature equal to or greater  
than the deformation temperature.

75. The method of claim 73 wherein the implant contacts a bone defect prior to  
25 deformation.

76. The method of claim 73 wherein the implant deforms prior to contacting the  
bone defect.

30 77. The method of claim 73 wherein stimulating induces the body to expand.

78. The method of claim 73 wherein stimulating induces the body to contract.

79. A method of preparing a self-forming orthopedic implant, said method comprising:  
fabricating an implant from a shape memory polymeric material, wherein said implant  
5 comprises a deformable body provided in an original configuration;  
deforming said body to a first configuration; and  
stimulating said body to induce the body to revert to the original configuration or a  
second configuration.

10

80. The method of claim 79 wherein the second configuration is substantially  
equivalent thereto to original configuration.

This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record

## BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☒ FADED TEXT OR DRAWING
- ☒ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☒ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: \_\_\_\_\_

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.